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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,940	11/06/2000	Richard M. Fike	0942.429006 (IVGN 174.2 C	7464
65482	7590	12/15/2006	EXAMINER	
INVITROGEN CORPORATION C/O INTELLEVATE P.O. BOX 52050 MINNEAPOLIS, MN 55402			SCHLAPKOHL, WALTER	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/705,940	<b>Applicant(s)</b> FIKE ET AL.	
	<b>Examiner</b> Walter Schlapkohl	<b>Art Unit</b> 1636	<i>mlf</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 9/29/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15, 16, 22-29, 31-34, 36-39, 41 and 44-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15-16, 22-29, 31-34, 36-39, 41 and 44-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                          |

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**DETAILED ACTION**

Receipt is acknowledged of the papers filed 9/29/2006 in which claims 40, 42-43, and 50-84 were cancelled and claims 1, 5-6, 15-16, 28, 41, 47 and 49 were amended. Claims 1-10, 15-16, 22-29, 31-34, 36-39, 41 and 44-49 are pending and under examination in the instant Office action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 15-16, 22-29, 31-34, 36-39, 41 and 44-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record.**

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*Response to Arguments*

It is Applicant's belief that the rejection focuses on the size of the genus that results from the combination of (1) different buffer salts with (2) different solvents. Therefore, in an effort to advance prosecution but not in acquiescence of the Examiner's rejection, Applicant has amended claim 1 to recite "reconstitution of said dry powder medium with a solvent comprising water."

Applicant's arguments have been carefully considered and are respectfully found unpersuasive. While the amendment to claim 1 to limit the encompassed solvents to those comprising water comes part way in addressing the rejection, the claims still contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Indeed, Applicant has amended claims 15-16 to include in a method of cultivating a eukaryotic cell, the limitation that the cell is contacted with a solution of the dry powder medium reconstituted with a solvent comprising water under conditions such that growth or differentiation of the eukaryotic cell occurs. Applicant's claims now encompass media and methods of making media that favor the differentiation of

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any eukaryotic cell. The amended claims still do not provide any structural or biochemical information with regard to the buffer salts and/or solvents comprising water which can be used in a culture medium such that the culture medium is a nutritive solution that supports the cultivation and/or growth and/or differentiation of any cell and such that the dry powder media is automatically pH adjusting. The examples in the specification are neither representative nor predictive of any other solvents used in combination with any set of buffer salts such that dry culture medium can be produced which supports the cultivation and/or growth and/or differentiation of any eukaryotic cell. Furthermore, the prior art does not appear to offset the deficiencies of the instant specification because it does not describe a set of methods for producing eukaryotic dry powder or a such media itself, such that any buffer salt(s) can be used with any solvent comprising water to produce a medium which is automatically pH-adjusting and which supports the cultivation and/or growth and/or differentiation of any eukaryotic cells.

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The rejection of claims 47 and 49 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because of the entry of new matter into the claims is hereby withdrawn in view of Applicant's amendment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-16, 22-27 & 44-45, and therefore dependent claim 41, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. **This rejection is maintained for reasons of record, but has been slightly altered in order to accommodate Applicant's amendment.**

Claim 15 recites "[a] method of cultivating a eukaryotic cell comprising preparing an automatically pH-adjusting eukaryotic dry powder culture medium prepared according to the method of claim 1, reconstituting the medium with a solvent comprising water to form a eukaryotic culture medium solution, and contacting a eukaryotic cell with said solution under conditions favoring growth or differentiation of the eukaryotic

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cell" in lines 1-6 (emphasis added). Claim 15 is vague and indefinite in that the metes and bounds of "conditions favoring growth or differentiation of the eukaryotic cell" are unclear. Does Applicant intend any conditions which favor growth or differentiation, which include, e.g., growth in a bioreactor and/or differentiation of primary stem cells *in vivo*; or does Applicant intend a more limited set of embodiments such as proliferation of cell lines *in vitro* in a culture dish?

Similarly, claim 16 recites "conditions favoring the growth or differentiation of the eukaryotic cell" in lines 3-4. Does Applicant intend any conditions which favor growth or differentiation, which include, e.g., growth in a bioreactor and/or differentiation of primary stem cells *in vivo*; or does Applicant intend a more limited set of embodiments such as proliferation of cell lines *in vitro* in a culture dish?

#### *Response to Arguments*

Applicant argues that the scope of the claimed subject matter of claims 22-27 and 44-45 would be readily apparent to one of ordinary skill in the art. Applicant further argues that the USPTO uses the term "derivative" without any guidance to the meaning of the term, when referring to various U.S. Patent Classifications related to cells. As an example, Applicant

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points to class 435, subclass 355 which encompasses "[s]ubject matter wherein the mouse cell is of blood or lymphatic origin" and cells of "blood or lymphatic origin or derivative" (emphasis added).

Applicant's arguments have been carefully considered but are respectfully found unpersuasive. Examiner agrees with Applicant insofar as some embodiments encompassed within Applicant's claimed eukaryotic cell "derived from" yeast cells, plant cells, animal cells, mammalian cells and human cells would readily be apparent to one of ordinary skill in the art. However, without a clear indication of the steps involved in the deriving or the structures/functions associated with the claimed derived cells, many embodiments would not be readily apparent to one of ordinary skill in the art. Applicant is reminded that the claims in a patent application must particularly point out and distinctly claim the subject matter which Applicant regards as his invention. Patent classification descriptions are not required to adhere to such a standard; therefore, comparisons between the claim language and language used in other printed material are not relevant.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-8, 10, 15-16, 22-29, 31-34, 36-39, 41 and 44-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigma catalog 1994 (of record). **This rejection is maintained for reasons of record.**

*Response to Arguments*

Applicant argues that SIGMA does not anticipate the present claims because it does not teach an automatically pH-adjusting eukaryotic dry powder culture medium having said desired final pH upon reconstitution and wherein the dry powder culture medium comprises sodium bicarbonate. In support of such argument, Applicant has provided product information documents which, according to Applicant, demonstrate that SIGMA does not teach a dry powder medium comprising sodium bicarbonate.

Applicant's arguments have been carefully considered and are respectfully found unpersuasive for the following reasons.

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The instant rejection of the claims under 35 U.S.C. 102(b) is based upon the teaching of a SIGMA 1994 catalog, not upon the product information documents provided by Applicant, and arguments which are drawn to documents other than the SIGMA reference are not relevant. Examiner invites Applicant to show where in the SIGMA reference it is taught that the addition of sodium bicarbonate is added to something other than the dry powder medium and where in the SIGMA reference it is taught that the dry powder media does not result in a desired pH upon reconstitution of the powder.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered

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therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10, 15-6, 22-29, 31-34, 36-39, 41 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over SIGMA Catalog 1994 (of record) in view of Fike et al (WO 98/36051; of record). **This rejection is maintained for reasons of record but has been slightly altered in order to accommodate Applicant's amendment.**

#### *Response to Arguments*

Applicant argues that SIGMA does not teach the determination of a ratio between monobasic and dibasic phosphate salts which gives a desired final pH upon reconstitution of the powder because the cited dry powder media in SIGMA do not result in a desired pH upon reconstitution of the powder. Applicant further argues that Examiner concedes that Fike et al do not specifically teach using pH-opposing forms of buffer salts to maintain the pH of the medium at a desired level.

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Applicant's arguments have been carefully considered but are respectfully found unpersuasive. Applicant's arguments concerning the SIGMA reference have been addressed above. Applicant's arguments with regard to the Fike reference are unpersuasive because the reference of Fike et al alone need not teach using pH-opposing forms of buffer salts to maintain the pH of the medium at a desired level. It is the combination of references which meet the claim limitations of the claims under rejection, as explained in the previous Office action.

#### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic

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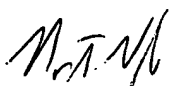
For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.  
Patent Examiner  
Art Unit 1636

December 5, 2006

  
NANCY VOGEL  
PRIMARY EXAMINER